DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 23, 2015

Donald W. Guthner
Orgenix LLC
111 Hill Road
Douglassville, PA 19518

Re: K143159
Trade/Device Name: Modular Models
P2ND1001 - Cannulated PediGuard® Needle#1 (165mm)
P2ND1002 - Cannulated PediGuard® Needle#2 (165mm)
P2ND1101 - Cannulated PediGuard® Needle (120mm)
P2HE1000 - Cannulated PediGuard® Handle
Single-Piece Models
P1-AU411 - PediGuard® Tri Tip Ø4.0mm
P1-AU412 - PediGuard® Tr Tip Ø3.2mm
P1-AU413 - PediGuard® Tri Tip Ø2.5mm
P1-AU414 - PediGuard® Ø2.5mm XS
P1-AU450 - PediGuard® Curv
P1-AU451 - PediGuard® Curv XS
Regulation Number: 21 CFR §874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: November 3, 2014
Received: November 3, 2014

Dear Dr. Guthner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143159

Device Name
Cannulated PediGuard® Needle - P2ND1001, P2ND1002, P2ND1101; Cannulated PediGuard® Handle - P2HE1000
PediGuard® Tri Tip - P1-AU411, P1-AU412, P1-AU413; PediGuard® Ø2.5mm XS - P1-AU414;
PediGuard® Curv - P1-AU450, P1-AU451

Indications for Use *(Describe)*
The PediGuard is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine.

The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SpineGuard's PediGuard®

Submitter:

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France
Phone: +(33) 1 45 18 45 19

Contact Person:

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Phone: 646-460-2984
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Date Prepared: December 19, 2014

Name of Device:

Modular Models

- P2ND1001 - Cannulated PediGuard® Needle#1 (165mm)
- P2ND1002 - Cannulated PediGuard® Needle#2 (165mm)
- P2ND1101 - Cannulated PediGuard® Needle (120mm)
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- P1-AU414 - PediGuard® Ø2.5mm XS
- P1-AU450 - PediGuard® Curv
- P1-AU451 - PediGuard® Curv XS

Common or Usual Name:	Nerve Stimulator
Classification Name:	Surgical Nerve Stimulator/Locator
Review Panel:	Neurology
Product Code:	PDQ and ETN
Device Class:	Class II
Regulation:	21 C.F.R. §874.1820

Predicate Devices

SpineGuard S.A., PediGuard Nerve Detector (K030526; K123390)

Device Description

The PediGuard® modular and single-piece devices are single use, devices composed of stainless steel and plastic, and are provided sterile. The PediGuard devices consist of a handle containing the electronics and a stainless steel shaft with distal sensor for measuring electrical impedance of the tissues immediately in contact with the sensor during use. The devices produce visual and audible signals to indicate changes in impedance associated with possible vertebral perforation.

All PediGuard® models provide real-time visual and auditory feedback to the surgeon during the preparation of the pedicle screw pilot holes, sounding an alert when the tip of the sensor senses a change in the impedance of the surrounding tissues, which may indicate that the tip is in contact with soft tissues and a possible vertebral cortex perforation.

Intended Use/Indications for Use

The PediGuard is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine.

The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.

Substantial Equivalence

The subject PediGuard® models are identical with the corresponding predicate models. No hardware or software changes were made to the current devices to prepare for the requested change to the Indications for Use statement. The only technological difference between the subject PediGuard and the predicate device is the introduction of a 120mm Cannulated PediGuard. The 120mm length device is identical in all aspects (materials, electronics, connectors and dimensions) to the cleared 160mm Cannulated PediGuard, with the exception of being shorter. These minor technological raise no new issues of safety or effectiveness. Thus, the subject PediGuard is substantially equivalent to the cleared predicated PediGuard (K123390).

Substantial Equivalence Chart

	Subject PediGuard® models	Cleared PediGuard® models (K123390)
Intended Use / Indications for Use	The PediGuard® is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that	The PediGuard® is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that

	indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.	indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.
Handle Shape	Gearshift T-Handle	Gearshift T-Handle
Components	Single Piece, Stainless Steel shaft, plastic handle, ceramic insulator or modular with removable handle	Single Piece, Stainless Steel shaft, plastic handle, ceramic insulator or modular with removable handle
Shaft Material	Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode and/or shaft: 304 Stainless Steel (ASTM F899), 316L Stainless Steel and/or 17-4PH (ASTM F899)	Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode and/or shaft: 304 Stainless Steel (ASTM F899), 316L Stainless Steel and/or 17-4PH (ASTM F899)
Safety Features	Device cannot be turned off until battery exhausted. Prevents reuse of device.	Device cannot be turned off until battery exhausted. Prevents reuse of device.
Power Source	Lithium-Ion Battery	Lithium-Ion Battery
Sterility	Sterile	Sterile
Single Use or Reusable	Single-use	Single-use
Distal Shaft shape	Curved or straight; or straight (cannulated) with removable inner starter stylet (optional) and sensory needle.	Curved or straight; or straight (cannulated) with removable inner starter stylet (optional) and sensory needle.
Dimensions	2.5mm shaft diameter / tapered for 2mm to 4mm; 3.0 mm shaft diameter (cannulated)	2.5mm shaft diameter / tapered for 2mm to 4mm; 3.0 mm shaft diameter (cannulated)
Circuit board	Capacitors, Resistors and Diodes - Firmware (programmable chip) on	Capacitors, Resistors and Diodes - Firmware (programmable chip) on

	circuit board	circuit board

Performance Data

The PediGuard® models conform to the following standards:

- ASTM F138-08, Standard specification for wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for surgical implants (UNS S31673) (Version 8) (2008).
- ASTM F899-1, Standard specification for wrought stainless steel for surgical instruments (Version 11) (2009).
- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety, Amendment 1, Amendment 2.
- IEC 60601-1-4, Medical Electrical Equipment - Part 1-4: General requirements for safety, Collateral Standard: Programmable electrical medical systems, Edition 1.1
- ISO 10993-5, Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity (1999).
- ISO 10993-10, Biological Evaluation of Medical Devices: Tests for irritation and sensitization.
- ISO 10993-11, Biological Evaluation of Medical Devices: Tests for systemic toxicity.
- ISO 11135-1, Sterilization of health care products - Ethylene oxide: Requirements for the development, validation and routine control of a sterilization process for medical devices (2007).
- ISO 10993-7, Biological evaluation of medical devices: Ethylene Oxide sterilization residuals (2008).
- ISO 11737-1, Sterilization of medical devices - Microbiological methods: Determination of a population of microorganisms on products (2006).
- ISO 11737-2, Sterilization of medical devices - Microbiological methods: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (2000).
- ISO 11607-1, Packaging for terminally sterilized medical devices: Requirements for materials, sterile barrier systems and packaging systems (2006).
- ISO 11607-2, Packaging for terminally sterilized medical devices: Validation requirements for forming, sealing and assembly processes (2006).
- ASTM F88, Standard test method for seal strength of flexible barrier materials (2009).
- ASTM F1929, Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- ASTM F1980, Standard guide for accelerated aging of sterile medical device packages (2007).
- ASTM D4169, Standard practice for performance testing of shipping containers and systems (2005).

In support of this clarification to the indications for use of the PediGuard, SpineGuard conducted a cadaver trial in which thoracolumbar pedicle screws were placed at T10-L5 level in cadavers. The

results show a 60% reduction in screw breach and an 86.8% reduction of total fluoroscopy shots when using the Cannulated PediGuard over use of the Jamshidi needle. In addition, the company submitted a clinical study of PediGuard in both open posterior pedicle screw fixation (PPSF) procedures and MIS posterior spine arthrodesis procedures. The results of this study showed no difference in optimal screw placement when using the PediGuard in either open or MIS surgery.

Conclusion

The PediGuard has the same intended use and similar indications for use and technological characteristics as the predicate PediGuard. As confirmed through bench and clinical testing data, the PediGuard® is as safe and effective for its intended use as its predicate device. Accordingly, the PediGuard is substantially equivalent.